

REMARKS

Claims 1-13 are pending and stand ready for further action on the merits. Claims 3, 8, 10, 12 and 13 have been amended for clarity. No new matter has been added by way of the above-amendment.

Election/Restriction

The Examiner has imposed a Restriction Requirement under 35 U.S.C. § 121 and has separated the claims into the following groups:

Group I, claims 1-12, drawn to a method of extraction (claims 1-10 and 12) and Vitamin E, squalene or phytosterols isolated using said extraction method (claim 11); and

Group II, claim 13, drawn to phytosterol crystals.

Applicants confirm the election of Group I consisting of claims 1-12, however, contrary to the Examiner's indication in the outstanding Office Action, this election is made *with traverse*.

According to MPEP §803, if the search and examination of an entire application can be made without a serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions. The Examiner has produced no evidence of the undue burden. Furthermore, since the Examiner has searched for claim 11, drawn to Vitamin E, squalene or phytosterols isolated using the extraction method of claim 1, there could be no burden to search for claim 13 (a subcategory of claim 11).

As such, Applicants respectfully request that the Examiner rejoins Group II with Group I.

Issues Under 35 USC § 112

Claims 1-12 are rejected under 35 USC 112, second paragraph for being indefinite. Applicants respectfully traverse the rejection.

The Examiner finds fault with the claims for not clearly describing the steps involved in the distillation of the "residue" or "distillate" obtained from the first short path distillation. In response, the claims have been amended to correct the errors found therein. The correct version is as stated in the specification wherein the second short path distillation step is carried out on the **residue** obtained from the first short path distillation step; the third short path distillation step is carried out on the **distillate** obtained from the second short path distillation step; and the saponification is carried out on the **residue** obtained from the third short path distillation step.

In view of the fact that the claims particularly point out and distinctly claim the subject matter which Applicants regard as the invention, withdrawal of the rejection is respectfully requested.

Issues Under 35 USC § 103

Claims 1-12 are rejected under 35 USC § 103 for being unpatentable over KirschenBauer (US 2,598,269 – hereinafter referred to as D1), Jacobs (US 6,838,104 – hereinafter referred to as D2), and Robinson et al. (US 6,057,462 – hereinafter referred to as D3). Applicants respectfully traverse the rejection.

Applicants respectfully submit that the Examiner has not followed the first two tenets set forth in MPEP 2141(II) for establishing a *prima facie* case of obviousness. The first two tenets are as follows:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination.

The Examiner first notes the differences between the teachings of D1 and the presently claimed extraction process in the following paragraph:

The instant claimed invention differs from the reference that the reference does not teach about the extraction of phytosterols by different short path distillations and then solvent extraction of unsaponifiable contents. The reference also does not teach about the extraction of phytosterols from saponified product via liquid-liquid extraction and then crystallization.

(See page 6, first full paragraph of the outstanding Office Action).

Then the Examiner picks and chooses from the teachings of D2 and D3 to cure these deficiencies. However, the Examiner neglects to take into consideration the differences in the compositions at each step in the process of D1 and the composition at each step in the process of D2 and D3. It is the theoretical equivalent of trying to fit a square peg in a round hole.

Each step of Applicants' extraction process has been well thought out and serves a purpose. It is Applicants' belief that if the Examiner views the inventive process as a whole (as required by the first tenet reproduced above in the obviousness analysis), the Examiner will not find that the combination of D1, D2 and D3 render the present invention obvious. MPEP 2142 further cautions as to impropriety of not taking into consideration the claimed invention "as a whole" in the following passage:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Applicants now turn to the specific distinctions between the present invention and the teachings of D1, D2 and D3 as a whole.

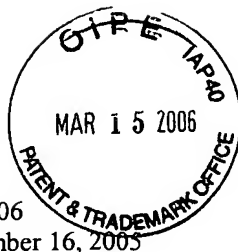
The process of present patent application aims to obtain vitamin E, sterols and squalene from palm oil. If the teachings of D1, D2 and D3 are combined in an attempt to achieve the same, then:

- i) fatty acid esters, instead of fatty acid distillate, would be used as the starting material in the process of D2;
- ii) the steps from solvent winterization onwards in the process of D2 [i.e. steps (d) and (e) of claim 5 in D2] would be substituted by the steps from alcohol/water addition onwards in the process of D3 [i.e. steps (c) to (g) of claim 1 in D3].

While (i), as mentioned above, is possible to be adopted, (ii) is not. The process of D3 only specifies steps for recovering sterols, hence if (ii) is adopted, it is not apparent how Vitamin E and squalene could be recovered.

Even when (i) and (ii) are adopted, the resultant process is different from the process of present patent application. Comparing the steps from alcohol/water addition onwards in the process of D3 with step (vi) as mentioned in claim 12 of the present patent application, the main difference is:

- For the process of D3, a solution of the neutrals of saponified tall oil pitch in hydrocarbon/alcohol/water is separated into a top phase which is a hydrocarbon layer and a bottom phase which is an alcohol/water layer and sterols are crystallized from the isolated hydrocarbon layer.
- For the process of present patent application, sterols are directly crystallized from a solution of unsaponifiable matters in hydrocarbon/alcohol/water without prior phase separation.
- Referring to Example 3 of the present patent application, the hexane (hydrocarbon) layer contains 41% squalene, 39.7% sterols and 12% vitamin E while the ethanol/water layer contains 9.3% squalene, 64.7% sterols and 20.4% vitamin E showing that the ethanol/water layer has higher content of sterols. To optimize recovery of vitamin E, sterols and squalene from palm oil, no phase separation step is conducted before the sterols crystallization step in the process of present patent application. The teachings in



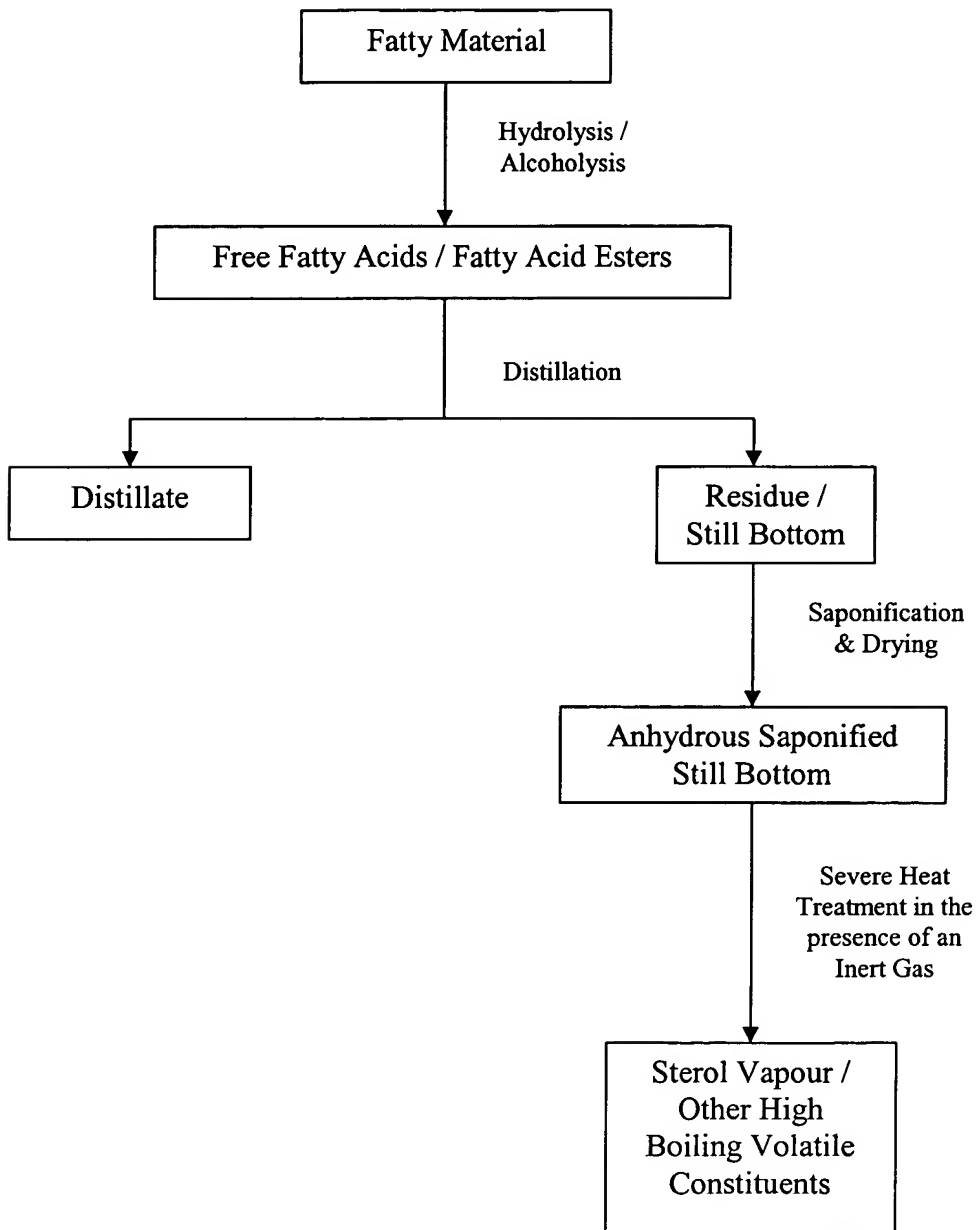
Application No. 10/642,596
Amendment dated March 15, 2006
Reply to Office Action of December 16, 2005

Docket No.: 3587-0110P

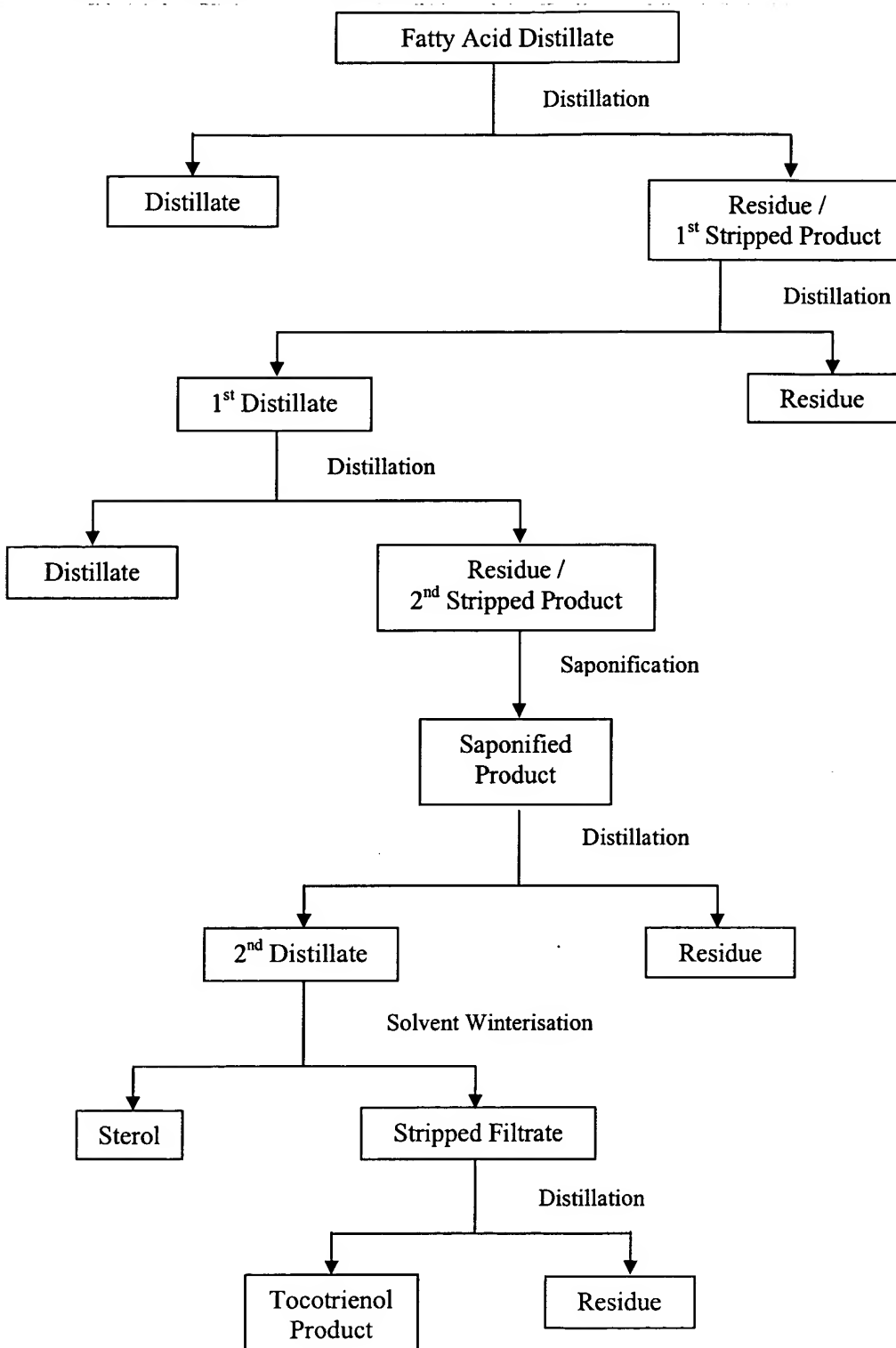
D3 are clearly different from those of the present patent application as D3 teaches that sterols are only crystallized from the isolated hydrocarbon layer.

For ease of comparison, flow diagrams of the processes of D1, D2 and D3 are enclosed herewith.

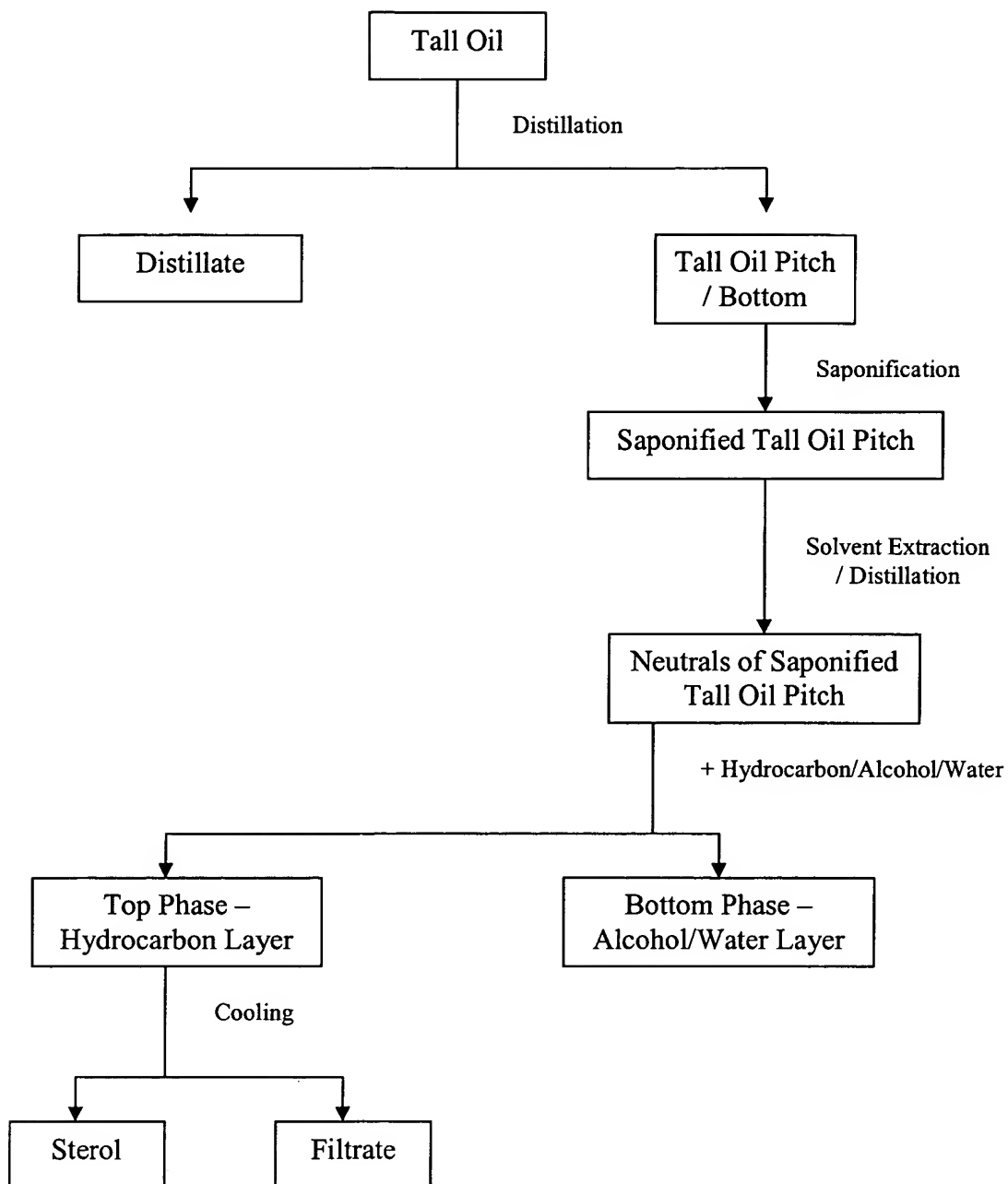
Process of D1 (KirschenBauer – US 2,598,269)



Process of D2 (Jacobs – US 6,838,104)



Process of D3 (Robinson – US 6,057,462)

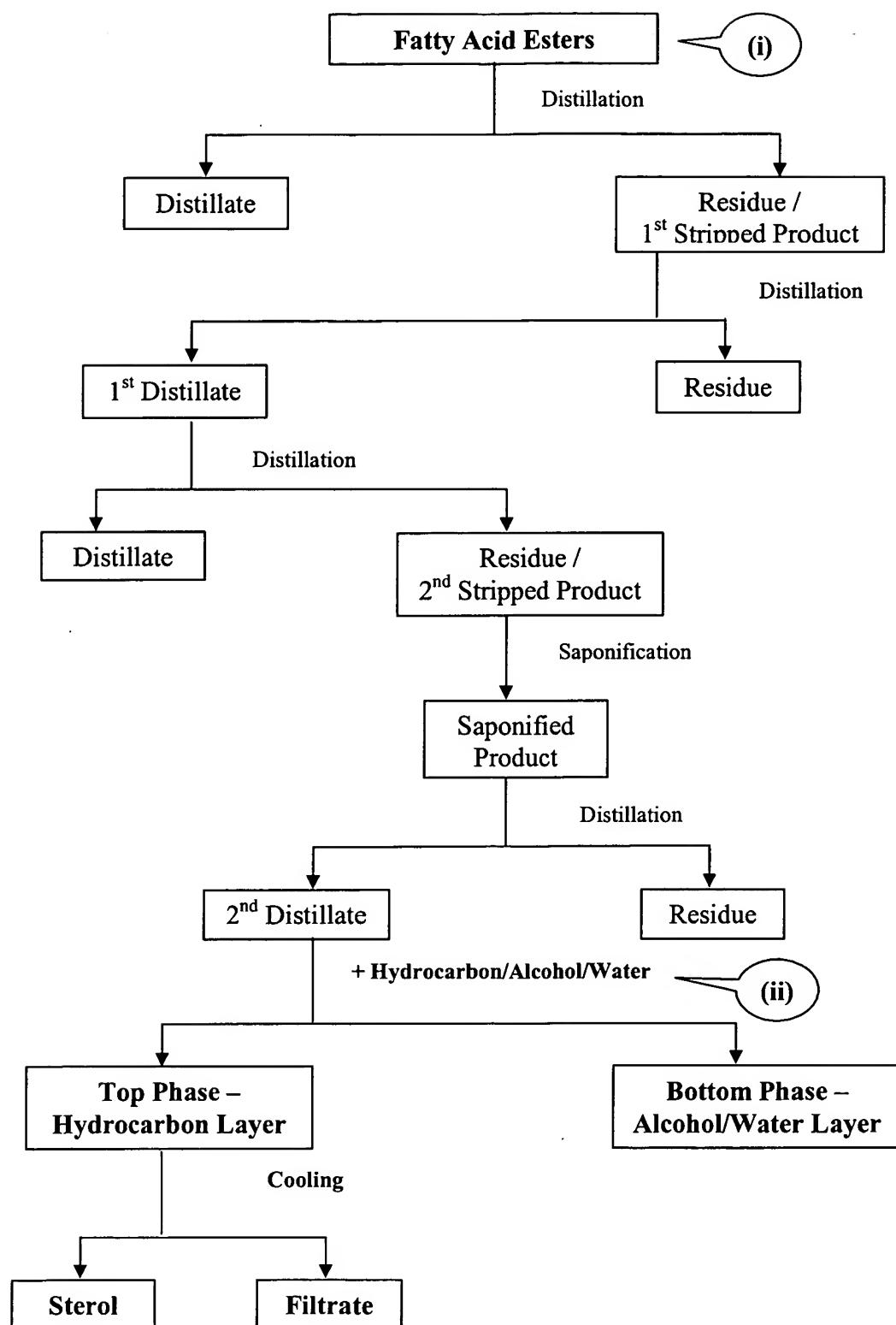


Thus, it is difficult to imagine that the inventive process would be found obvious by a skilled artisan given the apparent differences in the compositions at each step in the extraction processes of D1, D2 and D3.

As mentioned above, if the teachings of D1, D2 and D3 are combined in an attempt to achieve the instant process, then:

- i) fatty acid esters, instead of fatty acid distillate, would be used as the starting material in the process of D2;
- ii) the steps from solvent winterization onwards in the process of D2 [i.e. steps (d) and (e) of claim 5 in D2] would be substituted by the steps from alcohol/water addition onwards in the process of D3 [i.e. steps (c) to (g) of claim 1 in D3].

A flow diagram showing a process wherein (i) and (ii) are adopted is provided below:



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In view of the above-distinctions, Applicants urge the Examiner to reconsider the claimed invention *as a whole* in light of the combination of the references *as a whole*. For in so doing, it is believed that the Examiner will not find the present invention obvious.

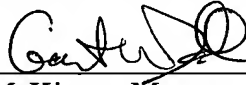
Withdrawal of the rejection is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., Esq. (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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Respectfully submitted,

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